

## Actions Taken by FDA Center for Veterinary Medicine

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The following corrections or additions to the January 2002 list were published in the Federal Register in April 2002.

### New Approvals

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**ANADA Number: 200-257**

Pioneer Product: 045-290  
Trade Name: Ketamine HCl  
Ingredients: Ketamine hydrochloride  
Sponsor: Vetrepharm Research, Inc.  
Approval Date: November 9, 2001  
Status: Prescription only  
Route: Intramuscular  
Species: Cats and subhuman primates  
Drug Form: Solution (liquid)  
Concentration: 100 milligrams per milliliter  
Indications: Used in cats for restraint or as the sole anesthetic agent for diagnostic or minor, brief, surgical procedures that do not require skeletal muscle relaxation. Used in subhuman primates for restraint.

*21CFR 522.1222a and 510.600*

**ANADA Number: 200-293**

Pioneer Product: 034-478  
Trade Name: Furosemide Injection 5%  
Ingredients: Furosemide  
Sponsor: Phoenix Scientific, Inc.  
Approval Date: December 18, 2001  
Status: Prescription only  
Route: Intramuscular, intravenous  
Species: Cattle, horses, dogs, and cats  
Drug Form: Liquid (solution)  
Concentration: 50 milligrams per milliliter  
Indications: **Cattle:** For the treatment of physiological parturient edema of the mammary gland and associated structures.  
**Dogs, cats and horses:** For the treatment of edema associated with cardiac insufficiency, acute noninflammatory tissue edema.  
Withdrawal: Cattle: 2 days; milk: 2 days

*21CFR 522.1010*

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### Supplemental Approvals

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**NADA Number: 111-636**

**This supplemental application provides for use of lincomycin hydrochloride soluble powder in the drinking water of swine weighing greater than 250 pounds for the treatment of swine dysentery.**

Trade Name: Lincomix® Soluble Powder  
Ingredients: Lincomycin hydrochloride  
Sponsor: Pharmacia and Upjohn Co.  
Approval Date: December 31, 2001  
Status: Over-the-counter  
Route: Oral  
Species: Swine, broiler chickens  
Drug Form: Powder  
Concentration: 16 grams lincomycin per 40 gram packet  
Indications: **Swine** – For the treatment of swine dysentery (bloody scours).  
**Broiler chickens** – For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.  
Tolerance: 21CFR 556.360 Lincomycin: The acceptable daily intake for total residues of lincomycin is 25 micrograms per kilogram of body weight per day. Tolerances for lincomycin in swine of 0.6 part per million in liver and 0.1 part per million in muscle are established. A tolerance for residues of lincomycin in chickens is not required.  
Withdrawal: Zero days

21CFR 520.1263c

**NADA Number: 140-872**

**This supplemental application provides for subcutaneous injection with no restriction on injection site.**

Trade Name: Posilac 1 Step®  
Ingredients: Sometribove zinc suspension  
Sponsor: Monsanto Company  
Approval Date: December 27, 2001  
Status: Over-the-counter  
Route: Subcutaneous  
Species: Lactating dairy cattle  
Drug Form: Liquid (suspension)  
Concentration: 500 milligrams per syringe  
Indications: For use in healthy lactating dairy cows to increase production of marketable milk.  
Withdrawal: Not required  
Patent Number: 5,013,713      Expiration date: May 7, 2008  
5,086,041      February 9, 2009  
5,411,951      February 9, 2009  
5,474,980      February 9, 2009  
5,595,971      February 9, 2009  
5,739,108      February 9, 2009  
Exclusivity: This product is not eligible for generic copying because it is a drug primarily manufactured using biotechnology.

21CFR 522.2112

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### **Addition of Sponsor**

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Vetrepharm Reasearch, Inc.  
119 Rowe Rd.  
Athens, GA 30601  
Drug Labeler Code: 064847

### **Change of Sponsor**

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**NADA Number: 039-077**

From: Boehringer Ingelheim Vetmedica, Inc.  
To: Alpharma, Inc.  
One Executive Dr.  
P.O. Box 1399  
Fort Lee, NJ 07024  
Drug labeler code: 046573

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